510(k) SUMMARY

Simavita Pty Limited's SIM™ System

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Simavita Pty Limited
Level 6, 56 Berry Street
North Sydney, NSW 2060
Australia

Phone: + 61 2 9331 7117
Facsimile: + 61 2 8088 1301

Contact Person: Peter Curran

AUG 2 2 2013

Date Prepared: July 9, 2013

Name of Device and Name/Address of Sponsor

Smart Incontinence Management (SIM™) System

Simavita Pty Limited
Level 6, 56 Berry Street
North Sydney, NSW 2060
Australia

Common or Usual Name

Enuresis Alarm

Classification Name

Conditioned Response Enuresis Alarm; 21 C.F.R. 876.2040

Predicate Devices

Health Sense International, Inc.'s Remote A'Lert (K943559)

Intended Use / Indications for Use

SIM™ (Smart Incontinence Management) is indicated for use by healthcare professionals to remotely monitor wetness events, and collect, transmit and report wetness events and other medical information from multiple patients within a clinical setting (e.g., hospitals, skilled nursing facilities, residential care facilities), to establish effective management care plans for continence events.

Technological Characteristics

SIM™ consists of disposable incontinence pads with embedded sensors, a wireless transceiver, hardware, and software.

Performance Data

SIM™ was subjected to biocompatibility testing, electrical safety and electromagnetic safety testing, standard testing for electrical equipment intended for measurement purposes, safety testing for information technology equipment, and other relevant performance testing. In all instances, SIM™ functioned as intended and the results observed were as expected

Substantial Equivalence

SIM™ is as safe and effective as the Remote A'Lert. SIM™ has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between SIM™ and its predicate devices raise no new questions of safety or effectiveness. Thus, SIM™ is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 22, 2013

Simavita Pty Limited
% John J. Smith, MD, JD
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, DC 20004

Re: K130951
Trade Name: SIM™ System
Classification Regulation Name and Number: 21 CFR§ 876.2040 – Enuresis alarm
Regulatory Class: Class II Exempt
Product Code: KPN
Dated: July 9, 2013
Received: July 9, 2013

Dear John J. Smith, MD, JD,

We have reviewed your premarket notification submission and have found this device to be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (Act). Therefore, you may immediately begin marketing this device as described in your premarket notification.

The final classification regulation for your device appears in Title 21 of the Code of Federal Regulations (CFR) 876.2040 – Enuresis Alarm. Your device's classification regulation name, regulatory class and product code are shown above. When listing your device with the Food and Drug Administration, please use this product code.

In the future, new but substantially equivalent devices which fall within the above classification regulation name and meet the classification criteria may be marketed without sending a premarket notification submission to the Food and Drug Administration. We suggest, however, that you review 21 CFR Section 876.9 to determine whether or not your new device (s) meets the limitations of exemption from Section 510(k) of the Act.

If you have any questions regarding this letter, please contact Tuan Nguyen, Ph.D. at (301)796-5174. If you have procedural questions, please contact the Division of Small

Manufacturers International and Consumer Assistance (DSMICA) at (301)796 7100 or at their toll free number (800)638 2041, or contact the 510k staff at (301)796 5640.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

Device Name: SIM™ System

Indications for Use: K130951

SIM™ (Smart Incontinence Management) is indicated for use by healthcare professionals to remotely monitor wetness events, and collect, transmit and report wetness events and other medical information from multiple patients within a clinical setting (e.g., hospitals, skilled nursing facilities, residential care facilities), to establish effective management care plans for continence events.

Prescription Use ___YES____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____No___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130951